Council of the European Union
General Secretariat

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	CULT	**CODEC**
	CYBER	**IA**

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INFORMATION

From:	General Secretariat of the Council
To:	European Competitiveness Fund
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund (ECF), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP] - Impact Assessment indicative check list

Based on the Interinstitutional Agreement (IIA) on Better Law-Making of 13 April 2016 and following a Coreper decision on examination of Commission impact assessments (IAs), (ST 6270/18) , it was agreed that IAs are to be examined at working party level with the help of an indicative checklist. To this end

and with a view to the discussions on the above proposal, delegations will find attached the indicative checklist, which is intended to help delegations prepare their views on the IA as part of their consideration of the Commission's proposal.

Please note that the checklist is purely indicative and non-exhaustive, and should be used in a flexible way taking into account what is relevant and appropriate for each legislative file. Delegations are not required to provide written replies, but can do so if they wish.

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Examination of Commission IAs in the Council

in the context of the consideration of Commission proposals

- Indicative Checklist for Working Party Chairs -

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Title of proposal	
Lead DG	

1. Context of the IA

a) Is the IA carried out at the initiative of the Commission, the Council, or the European Parliament?

☐ **Commission** ☐ **Council** ☐ **Parliament**

b) Is the policy context explained clearly?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) Is the legal basis of the initiative clear and appropriate?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

2. Problem definition

a) Are the existence, scale and consequences of the problem clearly demonstrated?

☐ Yes ☐ No ☐ Partly

Comments:

b) Is the analysis of the problem supported by evidence, including comments and studies submitted by Member States or stakeholders during consultations?

☐ Yes ☐ No ☐ Partly

Comments:

c) Is any gap in evidence acknowledged?

☐ Yes ☐ No ☐ Partly

Comments:

3. Methodology

Is an appropriate methodology applied? Are the methodological choices, limitations and uncertainties clearly set out?

☐ Yes ☐ No ☐ Partly

Comments:

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4. Policy objectives

a) Does the IA set out clear policy objectives, including general aims and more specific/operational objectives?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

b) Do the policy objectives correspond to the identified problems?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) Are the policy objectives consistent with the broad EU policy strategies and the Strategic Agenda?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

d) Are the objectives linked to measurable monitoring indicators?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

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5.	**Subsidiarity & Proportionality**

a) **Is the Union's competence clearly established?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

b) **Does the IA analyse whether the proposed action is consistent with the principle of subsidiarity, and are necessity and added value of EU action clearly demonstrated?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) **Does the IA analyse whether the proposed action is consistent with the principle of proportionality?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

d) **Does the IA take into account action already taken or planned at EU or MS level?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

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6. Policy Options

a) Which of the following options does the IA identify to meet the objectives?

(more than one answer is possible)

☐ **No EU action** ☐ **Policy alternatives**

☐ **Alternatives to regulation** ☐ **Further harmonization**

Comments:

b) Are the most affected public/stakeholders identified?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) Does the IA contain elements on how public and stakeholders consultations informed the policy options ?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

d) Where relevant, are there reasons given for discarding options that were favoured during public and stakeholders consultations?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

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7. Analysis of impacts

a) Are the criteria used to determine the impact of the different policy options transparent?

☐ **Yes** ☐ **No** **X Partly**

Comments:

1) The IA does not consider adequately the impact on efforts and costs for manufacturers due to discarding Module A for machinery listed in Annex IV. In consequence, for every machinery listed in Annex IV, a third party conformity assessment is necessary.

The reasoning "The evaluation of the MD also showed that obligatory third-party assessment does not add significant costs to industry. During the Commission evaluation of the internal market legislation for industrial products , economic operators indicated that, even though the obligation for mandatory third-party conformity assessment had been removed in the current version of the MD (until the last revision, the MD had required mandatory third-party conformity assessment for the categories of machinery in Annex IV), this had not necessarily led to a sudden reduction in demand for the services of notified bodies. Many manufacturers have continued to use the services of third parties 'voluntarily' for reputational reasons and to reassure their customers that their products are safe.**" is questionable.**

If the voluntary involvement of third-party conformity assessment has not lead to a massive reduction in demand, there is no need to change the existing concept. A mandatory involvement will lead to higher efforts and costs for those manufacturers, who have not involved a third-party.

In addition, the reasoning "There is discussion about whether the internal-checks option leads to safety concerns. On this issue, the Rapid Alert System for Non-Food Dangerous Products (Safety Gate/RAPEX) has shown over the years that some of the products falling under Annex IV of the MD were identified as not being compliant with the requirements of the MD and the relevant European standards" **is complemented by Note 91** "It has not been possible to find out the percentage of non-compliant products, or the number of accidents caused." **which is questionable too. Why should the existing concept being revised, if there do not exist any quantified data?**

2) The IA does not adequately consider the resulting effort for European Standardisation Organisation due to the changed structure, e.g. Annex IV will be Annex I in future. During the last revision it took several years for standardiser to revise the huge amount of more than 700 Type-C standards.

3) Additionally the changes in the structure of the current MD (e.g. renumbering of the Annexes) will lead to changes in the existing documentary structures of economic operators. The IA does not give sufficient data to the higher efforts and costs because of the necessary and obligatory update of documentary structures.

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b) Are the impacts of the different policy options set out in a comparable format?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) Where appropriate, are both the short and long-term costs and benefits of the different policy options taken into consideration?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

d) Are impacts on affected public and stakeholders clearly analysed, for each policy option, in particular for the selected option?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

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8. Specific aspects included in the IA	
Where applicable, indicate whether the impact has been sufficiently assessed, both in qualitative and quantified terms, and whether the data and evidence used were appropriate.	
a) Economic impacts	
Impacts on competition	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Impacts on consumers	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Impacts on competitiveness	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	

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Impacts on Small and Medium Enterprises, including micro-enterprises[1]	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Administrative burdens and compliance costs, especially for businesses	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Digital aspects (including on the development of the Digital Single Market)	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	
Futureproofing (degree to which proposal is future proof and innovation-friendly?)	
Sufficiently assessed	☐ **Yes** ☐ **No**
Based on appropriate data/evidence	☐ **Yes** ☐ **No**
If not, please elaborate:	

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[1] Impact assessments should assess SME impacts, and should also analyse the case for allowing (a) exemptions for micro-enterprises with <10 employees and <€2 mio turnover or balance sheet, and (b) lighter regimes for SMEs. See http://ec.europa.eu/governance/impact/key_docs/docs/meg_guidelines.pdf.

b) Social impacts[2]	
Sufficiently assessed	☐ Yes ☐ No
Based on appropriate data/evidence	☐ Yes ☐ No
If not, please elaborate:	

c) Environmental impacts[3]	
Sufficiently assessed	☐ Yes ☐ No
Based on appropriate data/evidence	☐ Yes ☐ No
If not, please elaborate:	

d) Impacts on individual Member States, regional or local authorities (territorial impacts)	
Sufficiently assessed	☐ Yes ☐ No
Based on appropriate data/evidence	☐ Yes ☐ No
If not, please elaborate:	

9. Opinion of the Regulatory Scrutiny Board[4] (RSB) of the Commission

Are the comments and recommendations of the RSB considered in the IA report?

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

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2 e.g. impacts on employment and labour markets, social inclusion and protection of particular groups, public health and safety, etc.
See also Guidance for assessing Social Impacts within the Commission Impact Assessment system (**http://ec.europa.eu/smart-regulation/impact/key_docs/docs/guidance_for_assessing_social_impacts.pdf**)

3 e.g. impacts on climate, air and water quality, use of the renewable or non-renewable resources, the likelihood or scale of environmental risks, use of energy etc.

4 Available by searching by Commission DG and date of publication at the following website http://ec.europa.eu/governance/impact/ia_carried_out/cia_2012_en.htm

10.	**Monitoring, transposition, compliance**

a) **Will the proposed indicators enable the intended effects to be measured?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

b) **Are those responsible for monitoring (and compliance) identified?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

c) **Are operational monitoring and evaluation arrangements proposed?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

d) **Does the IA address the impact of the proposed transposition deadline for MS ?**

☐ **Yes** ☐ **No** ☐ **Partly**

Comments:

11.	**Summary**

Main issues proposed for discussion during the WP meeting on the Commission's IA:

1.

2.

3.

etc.

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